STATUTORY INSTRUMENTS

2000 No. 2250

MEDICINES

The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2000

Made - - - -	*10th August 2000*
Laid before Parliament	*5th September 2000*
Coming into force	*1st October 2000*

The Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with health in England, the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, acting jointly, with the consent of the Treasury, in exercise of the powers conferred by section 1(1), (2) and (3)(b) of the Medicines Act 1971**(a)** and now vested in them**(b)**and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations**(c)**, and the Minister of Agriculture, Fisheries and Food and the Secretary of State, being Ministers designated**(d)** for the purpose of section 2(2) of the European Communities Act 1972**(e)** in relation to medicinal products and the common agricultural policy of the European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2000 and shall come into force on 1st October 2000.

(2) In these Regulations "the principal Regulations" means the Medicines (Products for Animal Use—Fees) Regulations 1998**(f)**.

(3) Unless the context otherwise requires, expressions used in these Regulations shall have the same meaning as in the principal Regulations.

(a) 1971 c. 69 as amended by section 21 of the Health and Medicines Act 1988 (c. 49); by virtue of section 1(3) of the 1971 Act expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67) as amended by article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388). The expression "the Ministers" is defined in section 1(1) of the 1968 Act as so amended.

(b) In the case of the Minister of Agriculture, Fisheries and Food, by virtue of articles 2(2) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I. 1999/3142); in the case of the Secretary of State concerned with health in England by virtue of articles 2(1) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999; in the case of the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, by virtue of section 95(5) of, and paragraph 10(1)(b) of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) and article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I. 1999/283 (N.I. 1)).

(c) *See* section 129(6) of the Medicines Act 1968 as extended to include Regulations made under the Medicines Act 1971 by section 1(3)(b) of that latter Act.

(d) S.I. 1972/1811.

(e) 1972 c. 68.

(f) S.I. 1998/2428; amended by S.I. 1999/2512.

Amendment of fees specified in the principal Regulations

2. In respect of each provision of the principal Regulations specified in the entries in column (1) (the subject matter of which is described in column (2)) of the Schedule to these Regulations, where a fee is specified opposite that provision in column (3) there shall be substituted the fee specified opposite that provision in column (4).

3.—(1) In Schedule 3 to the principal Regulations—

(a) in Part II, paragraph 1 (calculation of annual fees) there shall be substituted the figure "£269" for the figure "£262", the figure "£18,956" for the figure "£18,480", and the figure "0.451%" for the figure "0.44%";

(b) in Part II, paragraph 2 (calculation of annual fees) there shall be substituted the figure "0.677%" for the figure "0.66%"; and

(c) in Part III (calculation of annual fee—emergency vaccines) there shall be substituted the figure "0.677%" for the figure "0.66%".

Transitional provisions

4.—(1) Subject to paragraphs (2) and (3) below, these Regulations shall not apply in respect of any application made before the date these Regulations come into force.

(2) These Regulations shall apply in relation to any fee payable in respect of any inspection made after these Regulations come into force in connection with any application made before they come into force.

(3) Where, in connection with an application to renew a marketing authorisation, licence or certificate made before these Regulations come into force, the authorisation, licence or certificate is due to expire on or after the date these Regulations come into force, regulation 17(4) and (5) of the principal Regulations shall apply to that application on the basis that the fee payable for the application following the coming into force of these Regulations is the appropriate fee payable.

(4) Nothing in these Regulations shall have effect in relation to an annual fee relating to a calendar year earlier than 1999.

Hayman
Minister of State
1st August 2000 Ministry of Agriculture, Fisheries and Food

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State
5th August 2000 Department of Health

Bairbre de Brún
8th August 2000 Minister of Health, Social Services and Public Safety

Signed by authority of the Minister of Agriculture and Rural Development

Peter Small
Permanent Secretary
8th August 2000 Department of Agriculture and Rural Development

We consent,

Jim Dowd and Bob Ainsworth
10th August 2000 Two of the Lords Commissioners of Her Majesty's Treasury

SCHEDULE

Regulation 2

SUBSTITUTION OF FEES

Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
Provision in the principal Regulations	*Subject matter*	*Old fee*	*New fee*
regulation 12	Manufacturer's licences: annual fees	£200	£205
regulation 13	Wholesale dealer's licences: annual fees		
regulation 13(1)	Turnover of £40,000 or more	£400	£410
regulation 13(2)	Turnover of less than £40,000	£200	£205
regulation 14	Registration of Homoeopathic Veterinary Medicinal Products		
regulation 14(2)	Renewal of registration	£80	£80
regulation 14(3)	Alteration of dossier	£90	£90
SCHEDULE 1, PART II	**FEES RELATING TO APPLICATIONS FOR THE GRANT OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES**		
paragraph 1, Table A, Column (2)	Fee for an application for a type A marketing authorisation		
entry 1	Major application	£19,115	£19,595
entry 2	Complex application	£11,095	£11,370
entry 3	Standard application	£4,790	£4,910
entry 4	Abridged standard application	£3,740	£3,835
entry 5	Simple application	£1,330	£1,365
paragraph 1, Table A, Column (3)	Fee for an application for a type B marketing authorisation		
entry 1	Major application	£10,550	£10,815
entry 2	Complex application	£6,330	£6,490
entry 3	Standard application	£3,165	£3,245
entry 5	Simple application	£845	£865
paragraph 1, Table A, Column (4)	Fee for an application for a product licence		
entry 1	Major application	£19,115	£19,595
entry 2	Complex application	£11,095	£11,370
entry 3	Standard application	£4,790	£4,910
entry 5	Simple application	£1,330	£1,365
paragraph 2, Table B, Column (2)	Fee for an application for an Article 15.2 marketing authorisation		

Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
Provision in the principal Regulations	*Subject matter*	*Old fee*	*New fee*
entry 1	Major application	£11,095	£11,370
entry 2	Complex application	£4,790	£4,910
paragraph 3	Application for a marketing authorisation by holder of Article 15.2 marketing authorisation		
paragraph 3(a)	Major application previously made	£8,020	£8,225
paragraph 3(b)	Complex application previously made	£6,305	£6,460
paragraph 6	Manufacturer's licences		
paragraph 6(1)(a)	Applications in respect of which paragraph 6(2) applies	£100	£100
paragraph 6(1)(b)	Other cases	£2,150	£2,205
paragraph 7	Wholesale dealer's licences		
paragraph 7(1)	Application fee where anticipated turnover £40,000 or more	£1,250	£1,280
paragraph 7(2)	Application fee where anticipated turnover less than £40,000	£505	£520
paragraph 8	Animal test certificate applications in relation to biological products or for administration to non food-producing animals	£265	£270
paragraph 8	Other animal test certificate applications	£635	£650
paragraph 9	Marketing authorisation (parallel import)	£1,495	£1,530
SCHEDULE 1, PART III	**FEES RELATING TO APPLICATIONS FOR ASSISTANCE IN CONNECTION WITH MUTUAL RECOGNITION APPLICATIONS**		
paragraph 4, Table C, Column (2)	Basic fee		
entry 1	Major	£3,430	£3,515
entry 2	Complex	£2,295	£2,350
entry 3	Standard	£990	£1,015
entry 4	Simple	£330	£340
paragraph 4, Table C, Column (3)	Additional fee for the sixth and each additional member State		
entry 1	Major	£740	£760
entry 2	Complex	£360	£370
entry 3	Standard	£185	£190
entry 4	Simple	£65	£65
paragraph 5, Table D, Column (2)	Basic fee		

Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
Provision in the principal Regulations	*Subject matter*	*Old fee*	*New fee*
entry 1	Category I application	£8,415	£8,625
entry 2	Category II application	£5,615	£5,755
entry 3	Category III application	£4,490	£4,600
paragraph 5, Table D, Column (3)	Additional fee for the sixth and each additional member State		
entry 1	Category I application	£1,055	£1,080
entry 2	Category II application	£700	£720
entry 3	Category III application	£560	£575
SCHEDULE 1, PART IV	**FEES RELATING TO APPLICATIONS FOR THE VARIATION OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES**		
paragraph 1	Marketing authorisations (other than mutually recognised marketing authorisations) and product licences—complex application for variation	£2,110	£2,165
paragraph 2, Table E, Column (2)	Marketing authorisations (other than mutually recognised marketing authorisations) and product licences—application for variation other than complex application		
entry 1	Variation requiring assessment	£530	£545
entry 2	Variation not requiring assessment	£210	£215
paragraph 3, Table F, Column (2)	United Kingdom acting as the Reference Member State		
entry 1	Type 1 variation—Administrative	£560	£575
entry 2	Type I variation—Scientific	£2,245	£2,300
entry 3	Type I variation, Scientific—Type II procedure	£3,695	£3,785
entry 4	Type II variation	£7,855	£8,050
entry 5	Variation with extras	£8,980	£9,205
paragraph 3, Table F, Column (3)	United Kingdom not acting as the Reference Member State		
entry 1	Type 1 variation—Administrative	£105	£110
entry 2	Type I variation—Scientific	£530	£545
entry 3	Type I variation, Scientific—Type II procedure	£1,055	£1,080
entry 4	Type II variation	£2,110	£2,165

Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
Provision in the principal Regulations	*Subject matter*	*Old fee*	*New fee*
entry 5	Variation with extras	£3,755	£3,850
paragraph 5	Manufacturer's licences		
paragraph 5(a)	Variation of manufacturer's licence referred to in Schedule 1, Part II, paragraph 6(2)	£100	£100
paragraph 5(b)	Variation in any other case		
paragraph 5(b)(i)	Requiring assessment	£380	£390
paragraph 5(b)(ii)	Not requiring assessment	£125	£130
paragraph 6	Wholesale dealer's licences		
paragraph 6(a)	Variation requiring assessment	£380	£390
paragraph 6(b)	Variation not requiring assessment	£125	£130
paragraph 7	Variation of animal test certificate	£210	£215
SCHEDULE 1, PART V	**FEES RELATING TO APPLICATIONS FOR THE RENEWAL OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES AND ANIMAL TEST CERTIFICATES**		
paragraph 1	Marketing authorisations and product licences		
paragraph 1(b)	Herbal products	£315	£325
paragraph 1(c)	Other cases	£950	£975
paragraph 2	Manufacturer's licences	£95	£95
paragraph 3	Animal test certificates	£95	£95
SCHEDULE 2	**FEES RELATING TO SITE INSPECTIONS**		
paragraph 2(1), Table A, Column (2)			
entry 1	Supersite inspection	£8,850	£9,070
entry 2	Major inspection	£4,655	£4,770
entry 3	Standard inspection	£3,330	£3,415
entry 4	Minor inspection	£1,800	£1,845
paragraph 2(2), Table B, Column (2)			
entry 1	Supersite inspection	£14,670	£15,035
entry 2	Major inspection	£8,100	£8,305
entry 3	Standard inspection covering immunological Veterinary Medicinal Products	£5,285	£5,420
entry 4	Other standard inspection	£3,985	£4,085
entry 5	Minor inspection covering immunological Veterinary Medicinal Products	£2,720	£2,730
entry 6	Other minor inspection	£2,665	£2,730

Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
Provision in the principal Regulations	*Subject matter*	*Old fee*	*New fee*
paragraph 2(3), Table C, Column (2)			
entry 1	Supersite inspection	£6,425	£6,585
entry 2	Major inspection	£4,340	£4,450
entry 3	Standard inspection	£2,125	£2,180
entry 4	Minor inspection	£1,095	£1,125
paragraph 2(4)(b)	Site limited solely to manufacture and assembly of emergency vaccines	£105	£105
paragraph 3(1)	Either or both of premises and procedures for quality control of a biological product which is not a dormant product	£1,275	£1,305
SCHEDULE 5, PART II	**FEES RELATING TO APPLICATIONS FOR REGISTRATION OF HOMOEOPATHIC VETERINARY MEDICINAL PRODUCTS**		
paragraph 1, Table, Column (2)	Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks		
entry 1	Product both prepared solely from repeat stock and being of repeat formulation	£105	£110
entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	£315	£325
entry 3	Any other application	£530	£545
paragraph 1, Table, Column (3)	Fees for applications in respect of products prepared from more than 5 homoeopathic stocks		
entry 1	Product both prepared solely from repeat stock and being of repeat formulation	£265	£270
entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	£475	£485
entry 3	Any other application	£685	£700
paragraph 2	Equivalent product registered under Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994**(a)** or in an EEA State		
paragraph 2(i)	Product prepared from not more than 5 homoeopathic stocks	£105	£110

(a) S.I. 1994/105, amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592.

Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
Provision in the principal Regulations	*Subject matter*	*Old fee*	*New fee*
paragraph 2(ii)	Product prepared from more than 5 homoeopathic stocks	£265	£270
SCHEDULE 6	**MARKETING AUTHORISATIONS, PRODUCT LICENCES AND ANIMAL TEST CERTIFICATES: FEES FOR REFERENCES TO THE VETERINARY PRODUCTS COMMITTEE OR TO THE MEDICINES COMMISSION**		
paragraph 1, Table, Column (2)			
entry 1	Major Application	£1,500	£1,540
entry 2	Complex application	£865	£885
entry 3	Standard application	£400	£410
entry 4	Simple application	£150	£155
paragraph 2	Animal test certificate	£520	£535

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Animal Use—Fees) Regulations 1998 as amended by the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 1999 ("the principal Regulations"). The principal Regulations prescribe fees in connection with applications and inspections relating to:

(a) marketing authorisations under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (S.I. 1994/3142);

(b) licences and certificates granted under the Medicines Act 1968 in so far as they apply to medicinal products for animal use; and

(c) the registration of homoeopathic veterinary medicinal products.

In prescribing fees in relation to the 1994 Regulations, the principal Regulations as amended by these Regulations continue to supplement the 1994 Regulations in implementing Council Directive 93/40/EEC (OJ No. L 214, 24.8.93, p.31) which contains amendments to Council Directive 81/851/EEC (OJ No. L 317, 6.11.81, p.1).

Regulation 2 prescribes new fees in relation to the provisions of the principal Regulations set out in column (1) of the Schedule to these Regulations. The fees in the principal Regulations are set out in column (3) and the new fees prescribed by these Regulations in column (4) of the Schedule.

Regulation 3 amends Parts II and III of Schedule 3 (calculation of annual fees) to the principal Regulations by prescribing new fees and, where the fee is charged on a percentage of turnover, new percentage amounts.

The average level of fees payable under these Regulations is increased by 2.5% in comparison with the principal Regulations.

Regulation 4 provides that the Regulations, subject to the exceptions in regulation 4(2) and (3), apply to applications made after the Regulations come into force and do not affect annual fees relating to a calendar year earlier than 1999.

A Regulatory Impact Assessment has been prepared and a copy has been placed in the library of each House of Parliament. Copies may be obtained from the Veterinary Medicines Directorate, Woodham Lane, Addlestone, Surrey, KT15 3NB.

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